

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1426]

Agency Information Collection Activities; Proposed Collection; Comment Request; Emergency Health Surveys

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on emergency health surveys to obtain data from health professionals and medical-device-user facilities when FDA must quickly determine whether or not a problem with a medical device impacts the public health.

DATES: Submit written comments on the collection of information by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

OMB

Display Date	8-2-00
Publication Date	8-3-00
Certifier	S. Reese

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520) Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Emergency Health Surveys

Under section 519 of the Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(i)), FDA is authorized to require: (1) Manufacturers to report medical-device-related deaths, serious injuries, and malfunctions; and (2) user facilities to report device-related deaths directly to FDA and to manufacturers, and to report serious injuries to the manufacturer. Section 522 of the act (21 U.S.C. 360(l)) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health or gross deception of the consumer. Section 903(b)(2) of the act (21 U.S.C. 393(b)(2))

authorizes the Commissioner of Food and Drugs (the Commissioner) to implement general powers (including conducting research) to effectively carry out the mission of FDA. These sections of the act enable FDA to enhance consumer protection from risks associated with medical device usage that are not foreseen or apparent during the premarket notification and review process. Currently FDA monitors medical product related postmarket adverse events via both the mandatory and voluntary MedWatch Reporting Systems using FDA Forms 3500 and 3500A (OMB Control No. 0910-0281).

FDA is seeking OMB clearance to collect information via a series of surveys, thus implementing section 705(b) of the act and the Commissioner's authority as specified in section 903(b)(2) of the act. Participation in these surveys will be voluntary. This request covers emergency health surveys for general type medical facilities, specialized medical facilities (those known for cardiac surgery, obstetrics/gynecology services, pediatric services, etc.), and health professionals, but more typically risk managers working in medical facilities.

FDA will use the information gathered from these surveys to quickly obtain vital information from the appropriate clinical sources so that FDA may take appropriate public health or regulatory action. FDA projects 10 emergency health surveys per year with a sample of between 50 and 200 respondents per survey.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

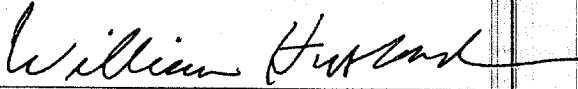
No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
200	10 (maximum)	2,000	2	4,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on the maximum sample size per questionnaire that FDA could analyze in a timely manner. The annual frequency of respondent was determined by the maximum number of questionnaires that will be sent to any individual respondent. Some respondents may be contacted only one time per year, while another respondent may be contacted several times, depending on the medical device under evaluation. It is estimated that, given the expected type

of issues that will be addressed by the surveys, at a maximum it will take 2 hours for a respondent to gather the requested information and fill in the answers.

Dated: July, 28, 2000



William K. Hubbard,
Senior Associate Commissioner
for Policy, Planning, and Legislation.

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